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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Andrew Gordon Johnston

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

WATTS, JENNA A

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/557,821	Applicant(s) JOHNSTON ET AL.	
	Examiner JENNA A. WATTS	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20060301</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding Claim 1 in particular, the phrase "feeding xylitol in liquid form into a mixer together with xylitol seed crystals" is unclear because it is unclear whether the liquid xylitol and the xylitol seed crystals are fed into the mixer concurrently or if the liquid xylitol is fed into the mixer first, followed by the xylitol seed crystals, which is how it appears to be stated in the specification on Page 5, in Example 1, where the liquid xylitol is fed into the mixer and the xylitol powder is also fed into the mixer.

Furthermore, the phrase "wherein the mixer is maintained at a temperature of between 80°C and 120°C" is unclear because it is unclear at which point in the process the mixer is maintained at this temperature range, either while the liquid xylitol and the xylitol seed crystals are being fed into the mixer, or when the liquid xylitol and seed crystals are being mixed, or when the seeded mass is being discharged from the mixer.

4. Furthermore, regarding Claim 1, the term "substantially prevented" in claim 1 is a relative term which renders the claim indefinite. The term "substantially prevented" is not defined by the claim, the specification does not provide a standard for ascertaining

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the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear to what extent the crystallization is prevented in the mixer by maintaining the mixer within the claimed temperature range.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oravainen et al. (Wipo Publication No. WO 91/07100, made of record by applicant).

9. Regarding Claims 1-5, Oravainen teaches a process for production of confectionary products comprising crystallized xylitol (Page 5, lines 15-20 and 33-35) comprising the steps of: feeding 35-80% by weight of molten xylitol which is capable of crystallization on cooling into a mixer together with a crystalline or xylitol in a powdered, solid or seed crystal form (Page 6, lines 1-6 and 25-30 and Page 9, 19-21). Oravainen teaches that the xylitol solid or seed crystals are added to the molten xylitol while mixing and teaches further mixing the combination to produce a mass (Page 6, lines 5-11 and Page 9, lines 15-17), which is deemed to be a seeded mass because Oravainen teaches the use of xylitol seed crystals. Oravainen further teaches discharging the seeded mass from the mixer (Page 9, lines 19-21), where the mixer is maintained at a temperature of between 95-135°C, which is partially within the claimed ranges of between 80°C and 120°C, 90°C and 120°C, 93°C and 100°C and 95°C and 97°C, whereby build up of crystallized xylitol within the mixer would be expected to be substantially prevented because Oravainen teaches that once the mass is discharged from the mixer and cooled on a cold table to 20 to 30°C, at which temperature the mass is kneaded to suitably regulate the crystallization (Page 9, lines 19-21). Reference is

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made to the 112 2nd rejection set forth above regarding when during the process the mixer is maintained at the claimed temperature range, and Oravainen is deemed to teach this claim limitation, because Oravainen teaches maintaining the mixer between 95-135°C during the mixing of the molten xylitol and xylitol seed crystals.

10. Oravainen is deemed to teach feeding the molten xylitol into a mixer together with the xylitol seed crystals because Oravainen teaches that the molten xylitol is present in the mixer when the seed crystals are added and mixed (Page 6, lines 1-6), and is thus placed or fed into a mixer together with xylitol seed crystals (Page 6, lines 1-6).

11. Oravainen does not specifically teach that the process is a continuous process.

12. However, it would have been obvious to one of ordinary skill in the art at the time of the invention, for the method of making a confectionary product comprising xylitol as taught by Oravainen, to have been affected in a continuous mode of operation in order to increase the efficiency and overall production capacity of the system. One of ordinary skill in the art would have been motivated to make the process of Oravainen run in a continuous mode in order to achieve maximum efficiency of the production system, thereby increasing financial returns.

13. Furthermore, according to the MPEP, the court has held that a claimed continuous operation would have been obvious in light of the batch process of the prior art. See MPEP 2144.04 V E.

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14. Regarding Claims 6-11, Oravainen is deemed to meet the claimed limitations because Claims 6-11 depend from Claim 5, which requires that the liquid xylitol is either molten xylitol or a low moisture xylitol syrup, and since Oravainen teaches molten xylitol, Oravainen is deemed to meet the limitations of Claims 6-11 as well as Claim 5.

15. Regarding Claims 12 and 13, teaches that the molten xylitol is present between 35 and 80% by weight of the total amount of sweetener used and the remainder of the sweetener is present in a crystalline or powder or seed crystal form (Page 6, lines 1-5), and also teaches that the xylitol and or other sugar alcohols stated or a mixture thereof can be used as the molten liquid and accordingly any of the components of the sweetener or a mixture thereof can be used as the solid component or seed crystals (Page 6, lines 25-30), thus, where the sugar alcohol is xylitol, and the molten xylitol is present in an amount between 35 and 80% by weight, Oravainen teaches that the remainder of the sweetener is present as seed crystals, thus Oravainen teaches that the ratio by weight of the molten xylitol to xylitol seed crystals fed into the mixer is between 90:10 and 50:50 or about 75% molten xylitol to about 25% xylitol seed crystals by weight.

16. Regarding Claims 14 and 15, Oravainen teaches that xylitol is melted at a temperature of 120 to 175°C (Page 6, lines 1-3), thus it can be seen that Oravainen teaches placing or feeding the molten xylitol into the mixer of between 92 and 200°C, and between 94 and 160°C.

17. Regarding Claim 17, Oravainen teaches that the mixing is effected with an efficient planetary or helical mixer (Page 9, lines 15-16), the planetary mixer being deemed a planetary agitator, because a mixer would also agitate and Applicant discloses that the mixer is equipped with a planetary agitator (see instant specification, Page 4, line 15).

18. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oravainen et al. (Wipo Publication No. WO 91/07100, made of record by Applicant) in view of DuRoss (U.S. Patent No. 5,139,795).

19. Oravainen is relied upon as cited above in the rejection of Claim 14.

20. Oravainen is taken as cited above in the rejection of Claims 14 and 15 and teaches that the molten xylitol is fed into the mixer between 120 and 175°C, but does not specifically teach that the molten xylitol is fed into the mixer at a temperature between 94 and 115°C.

21. DuRoss teach a process of making confectionary products containing crystallized xylitol (Column 2, lines 24-26) and teaches that as the temperature profile drops from molten feed temperature to discharge temperature, the viscosity of the melt increases due to the formation of crystals (Column 6, lines 8-11). DuRoss further teaches that care should be taken to ensure that the temperature of the emitted extrudate or mass is not too hot, as the molten mass will lose its shape and not only is such material difficult to handle, but the product obtained may be an undesirable mixture of crystals and

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amorphous glass (Column 6, lines 18-23). The problem can be corrected by decreasing the throughput time or jacket cooling temperature and other variables such as feed temperature, etc. (Column 6, lines 24-27).

22. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the feed temperature of the molten xylitol into the mixer in the method of making confectionary products, as taught by Oravainen, because DuRoss teaches that the feed temperature of the molten mass of xylitol is one variable that can be changed in order to ensure that the temperature of the molten mass upon discharge is not too hot, this being important because if the molten mass is too hot, it could result in a molten mass that loses its shape, and not only is such material difficult to handle, but the product obtained may be an undesirable mixture of crystals and amorphous glass. One of ordinary skill in the art would have been motivated by DuRoss to optimize the feed temperature of the molten xylitol into the mixer in order to ensure that the resulting molten mass is easy to handle, thus ensuring that the resulting confectionary products are of high quality and desirable to consumers.

Conclusion

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNA A. WATTS whose telephone number is (571) 270-7368. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

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24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. A. W./
J. Watts
Examiner, Art Unit 1794
June 3, 2009

/KEITH D. HENDRICKS/
Supervisory Patent Examiner, Art Unit 1794